FORM PTO-1449/A	and B	(modified	PTO/SB/08)
FURIVI P 1 U-1449/A	anu D	(moaniea	r i U/SD/Voi

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICATION NO.: 10/023,909 ATTY. DOCKET NO.: C1039.70058US00

FILING DATE: December 18, 2001

CONFIRMATION NO.: 8458

APPLICANT:

Davis et al.

Sheet As 1

of 12

GROUP ART UNIT: 1648 EXAMINER: Jeffrey S. Parkin

U.S. PATENT DOCUMENTS

Cite Initials No.		U.S. Patent Document		Name of Patentee or Applicant of Cited	Date of Publication or Issue	
Initials	No.	Number	Kind Code	Document	of Cited Document MM-DD-YYYY	
	A109	5,075,109		Tice et al.	12-24-1991	
	A110	5,543,152		Webb et al.	08-06-1996	
	A111	5,595,756		Bally et al.	01-21-1997	
•	A112	5,663,153		Hutcherson et al.	09-02-1997	
	A113	5,679,647		Carson et al.	10-21-1997	
	A114	5,705,385		Bally et al.	01-06-1998	
	A115	5,723,335		Hutcherson et al.	03-03-1998	
	A116	5,736,152		Dunn	04-07-1998	
	A117	5,753,613		Ansell et al.	05-19-1998	
	A118	5,766,920		Babbitt et al.	06-16-1998	
	A119	5,780,448		Davis	07-14-1998	
	A120	5,814,335		Webb et al.	09-29-1998	
	A121	5,965,542		Wasan et al.	10-12-1999	
	A122	5,976,567		Wheeler et al.	11-02-1999	
	A123	5,981,501		Wheeler et al.	11-09-1999	
	A124	6,004,534		Langer et al.	12-21-1999	
	A125	6,027,726		Ansell	02-22-2000	
•	A126	6,030,954		Wu et al.	02-29-2000	
	A127	6,042,838		Briles et al.	03-28-2000	
	A128	6,086,898		DeKruyff et al.	07-11-2000	
	A129	6,090,791		Sato et al.	07-18-2000	
	A130	6,110,745		Zhang et al.	08-29-2000	
·	A131	6,221,882	B1	Macfarlane	04-24-2001	
	A132	6,225,292	B1	Raz et al.	05-01-2001	
	A133	6,248,720	B1	Mathiowitz et al.	06-19-2001	
	A134	6,399,630	B1	Macfarlane	06-04-2002	
	A135	6,479,504	B1	Macfarlane et al.	11-12-2002	
	A136	6,498,148	Bl	Raz	12-24-2002	
	A137	6,521,637	B2	Macfarlane	02-18-2003	
	A138	6,610,308	B1	Haensler	08-26-2003	
	A139	6,620,805	B1	Takle et al.	09-16-2003	
	A140	6,693,086	B1	Dow et al.	02-17-2004	

EXAMINER:	DATE CONSIDERED:

<sup>#</sup> EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)			PPLIC.	ATION NO.: 10/023,909	ATTY. DOC	KET NO.: C1039.70058US00		
		ON DISCLOSUI	FI	FILING DATE: December 18, 2001 CONFIRMATION NO.: 8458				
STATEMENT BY APPLICANT			APPLICANT: Davis et al.					
Sheet	2	of 12	G)	ROUP	ART UNIT: 1648	EXAMINER	: Jeffrey S. Parkin	
<u> </u>			1	-	- <del>-</del> -	•		
	A141	6,737,066	B1		Moss		05-18-2004	
-	A142	6,821,957	B1		Krieg et al.		11-23-2004	
	A143	6,835,395	B1		Semple et al.		12-28-2004	
	A144	6,893,821	B2		Raz et al.		05-17-2005	
	A145	6,943,240	B2		Bauer et al.		09-13-2005	
	A146	6,949,520	B1		Hartmann et al.		09-27-2005	
	A147	7,001,890	B1		Wagner et al.		02-21-2006	
•	A148	7,049,302	B1		Kensil		05-23-2006	
	A149	7,129,222	B2		Van Nest et al.		10-31-2006	
	A150	7,223,741	B2		Krieg		05-29-2007	
	A151	2001-0034330	A1				10-25-2001	
	A152	2002-0009457	A1		Bowersock et al.		01-24-2002	
	A153	2003-0078223	A1	Raz et al.			04-24-2003	
	A154	2003-0092663	A1		Raz et al.		05-15-2003	
	A155	2003-0104044	A1		Semple et al.		06-05-2003	
	A156	2003-0119774	A1		Foldvari et al.		06-26-2003	
	A157	2003-0165478	A1		Sokoll et al.		09-04-2003	
	A158	2003-0232856	A1		Macfarlane		12-18-2003	
	A159	2004-0013688	A1		Wise et al.		01-22-2004	
	A160	2004-0006010	A1		Carson et al.		01-08-2004	
	A161	2004-0047869	A1	,	Garcon et al.		03-11-2004	
	A162	2004-0067902	A9		Bratzler et al.		04-08-2004	
	A163	2004-0092468	A1		Schwartz et al.		05-13-2004	
	A164	2004-0198680	A1		Krieg		10-07-2004	
	A165	2004-0229835	A1		Krieg et al.		11-18-2004	
	A166	2004-0234512	A1		Wagner et al.		11-25-2004	
	A167	2004-0235770	A1		Davis et al.		11-25-2004	
	A168	2004-0235774	A1		Bratzler et al.		11-25-2004	
<del></del>	A169	2004-0235777	A1	P 1	Wagner et al.		11-25-2004	
	A170	2004-0235778	A1		Wagner et al.		11-25-2004	
	A171	2004-0247662	A1		Dow et al.		12-09-2004	
	A172	2004-0266719	A1		McCluskie et al.		12-30-2004	
	A173	2005-0004061	A1		Krieg et al.		01-06-2005	
	A174	2005-0004062	A1		Krieg et al.		01-06-2005	
	A175	2005-0009774	A1		Krieg et al.		01-13-2005	
	A176	2005-0013812	A1		Dow et al.		01-20-2005	
			•					

EXAMINER:	DATE CONSIDERED:

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)			APPLIC	ATION NO.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US	
	INFORMATION DISCLOSURE		FILING	DATE: December 18, 2001	CONFIRMATION NO.: 8458	
_		BY APPLI		APPLIC	ANT: Davis et al.	
Sheet	3	of	12	GROUP	ART UNIT: 1648	EXAMINER: Jeffrey S. Parkir
	A177	2005-003273	4	Al	Davis et al.	02-10-2005
	A178	2005-003273	6	A1	Krieg et al.	02-10-2005
	A179	2005-003740	3	A1	Krieg et al.	02-17-2005
	A180	2005-003798	5	A1	Krieg et al.	02-17-2005
	A181	2005-004352		A1	Davis et al.	02-24-2005
•	A182	2005-004921	5	A1	Krieg et al.	03-03-2005
	A183	2005-004921		Al	Krieg et al.	03-03-2005
-	A184	2005-005460	,	A1	Wagner et al.	03-10-2005
	A185	2005-005460		A1	Krieg et al.	03-10-2005
	A186	2005-005961	9	A1	Krieg et al.	03-17-2005
	A187	2005-005962	25	A1	Krieg et al.	03-17-2005
	A188	2005-007049	1	A1	Krieg et al.	03-31-2005
<del></del>	A189	2005-007530	)2	A1	Hutcherson et al.	04-07-2005
·····	A190	2005-010098	3	A1	Bauer et al.	05-12-2005
	A191	2005-010155	4	A1	Krieg et al.	05-12-2005
<u> </u>	A192	2005-010155	7	A1	Krieg et al.	05-12-2005
	A193	2005-011927	<sup>'</sup> 3	Al	Lipford et al.	06-02-2005
	A194	2005-012352	23	Al	Krieg et al.	06-09-2005
	A195	2005-013091	1	A1	Uhlmann et al.	06-16-2005
	A196	2005-014853	7	Al	Krieg et al.	07-07-2005
	A197	2005-016988	8	A1	Hartman et al.	08-04-2005
	A198	2005-017104	7	Al	Krieg et al.	08-04-2005
	A199	2005-017667	2	A1	Scheule et al.	08-11-2005
	A200	2005-018142	:2	A1	Bauer et al.	08-18-2005
	A201	2005-018201	7	A1	Krieg	08-18-2005
	A202	2005-019134	2	Al	Tam et al.	09-01-2005
	A203	2005-019731	4	Al	Krieg et al.	09-08-2005
	A204	2005-020918	34	A1	Klinman et al.	09-22-2005
	A205	2005-021435	5	Al	Klinman et al.	09-29-2005
	A206	2005-021550	)1	A1	Lipford et al.	09-29-2005
	A207	2005-023399	)5	A1	Krieg et al.	10-20-2005
	A208	2005-023399	19	Al	Krieg et al.	10-20-2005
	A209	2005-023973	2	A1	Krieg et al.	10-27-2005
	A210	2005-023973	3	A1	Jurk et al.	10-27-2005
	A211	2005-023973	4	Al	Uhlmann et al.	10-27-2005
	A212	2005-023973	6	Al	Krieg et al.	10-27-2005
		<del></del>				

<sup>#</sup> EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)				APPLI	CATION NO.: 10/023,909	ATTY. DOCK	ATTY. DOCKET NO.: C1039.70058US00	
	INFORMATION DISCLOSURE			FILING	G DATE: December 18, 2001	CONFIRMAT	TION NO.: 8458	
	STATEMENT BY APPLICANT		APPLI	CANT: Davis et al.				
		T . T		GROU	P ART UNIT: 1648	EXAMINER:	Jeffrey S. Parkin	
Sheet	4	of	12		**		•	
	1 4010	2005-024437	0	T 4.1			11 02 2005	
	A213			Al	Krieg et al.		11-03-2005	
	A214	2005-024438	,	Al	Krieg et al.		11-03-2005	
	A215	2005-024547		Al	Krieg et al.		11-03-2005	
	A216	2005-024979		A1	Semple et al.		11-10-2005	
· · · · · · · · · · · · · · · · · · ·	A217	2005-025072		Al	Krieg et al.		11-10-2005	
	A218	2005-025607		Al	Lipford et al.		11-17-2005	
	A219	2005-026706		Al	Krieg et al.		12-01-2005	
•	A220	2005-027760		Al	Krieg et al.		12-15-2005	
	A221	2005-027760		A1	Krieg et al.		12-15-2005	
	A222	2006-000395		Al	Krieg et al.		01-05-2006	
	A223	2006-000396		Al	Ahluwalia et al.		01-05-2006	
· · · · · · · · · · · · · · · · · · ·	A224	2006-001991		Al	Krieg et al.		01-26-2006	
	A225	2006-001992	3	Al	Davis et al.		01-26-2006	
	A226	2006-005825	1	A1	Krieg et al.		03-16-2006	
	A227	2006-008932	6	A1	Krieg et al.		04-27-2006	
	A228	2006-009468	3	Al	Krieg et al.		05-04-2006	
	A229	2006-014087	5	A1	Krieg et al.		06-29-2006	
	A230	2006-015489	0	A1	Bratzler et al.		07-13-2006	
	A231	2006-017296	6	A1	Lipford et al.		08-03-2006	
	A232	2006-018891	3	A1	Krieg et al.		08-24-2006	
	A233	2006-021163	9	A1	Bratzler et al.		09-21-2006	
	A234	2006-021164	4	A1	Krieg et al.		09-21-2006	
	A235	2006-022376	9	A1	Dow et al.		10-05-2006	
	A236	2006-022927	1	A1	Krieg et al.		10-12-2006	
	A237	2006-024107	6	A1	Uhlmann et al.	i	10-26-2006	
	A238	2006-024603	5	A1	Ahluwalia et al.		11-02-2006	
···	A239	2006-025162	3	A1	Bachmann et al.		11-09-2006	
	A240	2006-025167	7	Al	Bachmann et al.		11-09-2006	
	A241	2006-028607	0	Al	Hartmann et al.		12-21-2006	
	A242	2006-028726		Al	Davis et al.		12-21-2006	
	A243	2007-000948		A1	Krieg et al.		01-11-2007	
	A244	2007-001047		A1	Krieg et al.		01-11-2007	
	A245	2007-003776		Al	Bratzler et al.		02-15-2007	
	A246	2007-006546		A1	Krieg et al.		03-22-2007	
	A247	2007-006655		Al	Krieg et al.		03-22-2007	
	A248	2007-006655		Al	Krieg et al.		03-22-2007	
	11270	1 200, 000000	•	1 ***	12108 00 01.		V3 22 2007	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or notitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)				APPLIC	ATION NO.: 10/023,909	ATTY. DOC	KET NO.: C1039.7	0058US00
INFORMATION DISCLOSURE			FILING					
		ENT BY APPLICANT APPLICANT: Davis et al.						
Sheet	5	of	12	GROUP	ART UNIT: 1648	EXAMINER	: Jeffrey	S. Parkin
		l	2124		T			
· · · · · · · · · · · · · · · · · · ·	A249	2007-007		A1	Krieg et al.		04-05-2007	
	A250	2007-012		A9	Davis et al.		06-07-2007	
	A251	2007-014		A1	Forsbach et al.		06-21-2007	
	A252	2007-018		A1	Wagner et al.		08-09-2007	
	A253	2007-020	2128	A1	Krieg et al.		08-30-2007	
•				FOREI	GN PATENT DOCUMENTS			
Examiner's Initials #	Cite No.	Office/	eign Patent Docur	Kind	Name of Patentee or Applicar Document	nt of Cited	Date of Publication of Cited Document	Translation (Y/N)
		Country		Code	n		MM-DD-YYYY	
	B27	WO	98/29557	A1	Biovector Therapeutics INEX Pharmaceuticals Corp. INEX Pharmaceuticals Corporation INEX Pharmaceuticals Corporation SmithKline Beecham Biologicals, S.A. IOMAI Corporation		07-09-1998	
	B28	WO	98/51278	A2			11-19-1998	
	B29	WO	99/30686	A1			06-24-1999	
	B30	WO	99/33493	A1			07-08-1999	
·····	B31	WO	99/33868	A2			07-08-1999	
	B32	WO	99/43350	Al			09-02-1999	
	B33	WO	99/52549	A1	SmithKline Beecham Biologic		10-29-1999	
	B34	WO	99/55743	A1	INEX Pharmaceuticals Corpor		11-04-1999	
	B35	WO	00/06588	A1	University of Iowa Research F		02-10-2000	
	B36	WO	00/14217	A2	CPG Immunopharmaceuticals		03-16-2000	
	B37	WO	00/67023	A1	CPG Immunopharmaceuticals	_	11-09-2000	
· · · · · · · · · · · · · · · · · · ·	B38	WO	2004/026888	A2	Coley Pharmaceutical GMBH	······································	04-01-2004	
	B39	WO	2004/094671	A2	Coley Pharmaceutical GMBH		11-04-2004	
	B40	WO	2006/080946	A2	Coley Pharmaceutical GMBH		08-03-2006	
	B41	WO	2007/031877	A2	Coley Pharmaceutical GMBH		03-22-2007	
-	B42	WO	2007/038720	A2	Coley Pharmaceutical GMBH		04-05-2007	
	<b>Y</b>	·			PATENT LITERATURE DOCU			
Examiner's Initials #	Cite No			thor (in CAPITAL LETTERS), title of the article (when appropriate), title of the item al, serial, symposium, eatalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
	C26	Strategy"		anuary 2007, "Coley Pharmaceutical Group Updates Hepatitis C Drug Developme				
	C27	Clinical 7			narmaceutical Group Announces bined with Cytotoxic Chemother			
EXAMINER:					DATE CONSIDERED			

<sup>#</sup> EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)  INFORMATION DISCLOSURE STATEMENT BY APPLICANT			APPLICATION NO	D.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US00		
			FILING DATE:	December 18, 2001	CONFIRMATION NO.: 8458		
			APPLICANT:	Davis et al.			
				GROUP ART UNIT	г: 1648	EXAMINER:	Inffrage C. Dowlein
Sheet	6	of	12	GROOF ART UNIT	1. 1040	EAAWIINEK:	Jeffrey S. Parkin

	C28	AGRAWAL et al., Pharmacokinetics of antisense oligonucleotides. Clin Pharmacokinet. 1995 Jan;28(1):7-16.	,,,,
	C29	AGRAWAL et al., Chapter 19: Pharmacokinetics and bioavailability of antisense oligonucleotides following oral and colorectal administrations in experimental animals. 1998: 525-43.	
	C30	AGRAWAL et al., Antisense oligonucleotides: towards clinical trials. Trends in Biotechnology, 1996; 14: 376-87.	
	C31	ALPAR et al., Potential of particulate carriers for the mucosal delivery of DNA vaccines. Biochem Soc Trans. 1997 May;25(2):337S.	
•	C32	ANITESCU et al., Interleukin-10 functions in vitro and in vivo to inhibit bacterial DNA-induced secretion of interleukin-12. J Interferon Cytokine Res. 1997 Dec;17(12):781-8.	
	C33	BAUER et al., DNA activates human immune cells through a CpG sequence-dependent manner. Immunology. 1999 Aug;97(4):699-705.	·
,	C34	BENNETT, Intracellular delivery of oligonucleotides with cationic liposomes. In: Delivery Strategies for Antisense Oligonucleotide Therapeutics. Akthar, Ed. 1995:223-32.	···
,	C35	BOWERSOCK et al., Evaluation of an orally administered vaccine, using hydrogels containing bacterial exotoxins of Pasteurella haemolytica, in cattle. Am J Vet Res. 1994 Apr;55(4):502-9.	
	C36	BRAZOLOT MILLAN et al., CpG DNA can induce strong Th1 humoral and cell-mediated immune responses against hepatitis B surface antigen in young mice. Proc Natl Acad Sci U S A. 1998 Dec 22;95(26):15553-8.	
	C37	BROIDE et al., DNA-Based immunization for asthma. Int Arch Allergy Immunol. 1999 Feb- Apr;118(2-4):453-6.	
	C38	CARSON et al., Oligonucleotide adjuvants for T helper 1 (Th1)-specific vaccination. J Exp Med. 1997 Nov 17;186(10):1621-2.	
	C39	CHACE et al., Bacterial DNA-induced NK cell IFN-gamma production is dependent on macrophage secretion of IL-12. Clin Immunol Immunopathol. 1997 Aug;84(2):185-93.	
	C40	CHELVARAJAN et al., CpG oligodeoxynucleotides overcome the unresponsiveness of neonatal B cells to stimulation with the thymus-independent stimuli anti-IgM and TNP-Ficoll. Eur J Immunol. 1999 Sep;29(9):2808-18.	
	C41	CHEN et al., Protective immunity induced by oral immunization with a rotavirus DNA vaccine encapsulated in microparticles. J Virol. 1998 Jul;72(7):5757-61.	
	C42	CHU et al., CpG oligodeoxynucleotides down-regulate macrophage class II MHC antigen processing. J Immunol. 1999 Aug 1;163(3):1188-94.	
	C43	CROOKE et al., Phosphorothioate Oligonucleotides. Therapeut Apps. 1995;ch5:63-84.	
	C44	CRYZ et al., European Commission COST/STD Initiative. Report of the expert panel VII. Vaccine delivery systems. Vaccine. 1996 May;14(7):665-90.	
	C45	DAVIS et al., DNA vaccines for prophylactic or therapeutic immunization against hepatitis B virus.  Mt Sinai J Med. 1999 Mar;66(2):84-90. Review.	
	C46	DELONG et al., Characterization of complexes of oligonucleotides with polyamidoamine starburst dendrimers and effects on intracellular delivery. J Pharm Sci. 1997 Jun;86(6):762-4. Abstract Only.	<del></del>
	C47	ELDRIDGE et al., Biodegradable microspheres as a vaccine delivery system. Mol Immunol. 1991 Mar;28(3):287-94. Abstract Only.	
	C48	EMI et al., Gene transfer mediated by polyarginine requires a formation of big carrier-complex of DNA aggregate. Biochem Biophys Res Commun. 1997 Feb 13;231(2):421-4.	

EXAMINER:	DATE CONSIDERED:

<sup>#</sup> EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)  INFORMATION DISCLOSURE STATEMENT BY APPLICANT			APPLICATION NO	D.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US00		
			FILING DATE:	December 18, 2001	CONFIRMATION	CONFIRMATION NO.: 8458	
			APPLICANT:	Davis et al.			
Sheet	7	of	12	GROUP ART UNIT	Г: 1648	EXAMINER:	Jeffrey S. Parkin

	·
C49	ETCHART et al., Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin. J Gen Virol. 1997 Jul;78 ( Pt 7):1577-80.
C50	FILION et al., Major limitations in the use of cationic liposomes for DNA delivery. Int J Pharmaceut. 1998; 162:159-70.
C51	FRALEY et al., New generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids. Trends Biochem Sci. 1981;6:77-80.
. C52	GALLICHAN et al., Specific secretory immune responses in the female genital tract following intranasal immunization with a recombinant adenovirus expressing glycoprotein B of herpes simplex virus. Vaccine. 1995 Nov;13(16):1589-95.
C53	protein using DNA-based vaccines augmented with cytokine-expressing plasmids. J Immunol. 1997 Feb 1;158(3):1231-7.
C54	GRAMZINSKI et al., Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration. Mol Med. 1998 Feb;4(2):109-18.
C55	
C56	GREGORIADIS et al., Engineering liposomes for drug delivery: progress and problems. Trends Biotechnol. 1995 Dec;13(12):527-37.
C57	HANEBERG et al., Induction of specific immunoglobulin A in the small intestine, colon-rectum, and vagina measured by a new method for collection of secretions from local mucosal surfaces.  Infect Immun. 1994 Jan;62(1):15-23.
C58	HARTMANN et al., CpG DNA and LPS induce distinct patterns of activation in human monocytes. Gene Ther. 1999 May;6(5):893-903.
C59	HARTMANN et al., Spontaneous and cationic lipid-mediated uptake of antisense oligonucleotides in human monocytes and lymphocytes. J Pharmacol Exp Ther. 1998 May;285(2):920-8.
C60	HARTMANN et al., CpG DNA: a potent signal for growth, activation, and maturation of human dendritic cells. Proc Natl Acad Sci U S A. 1999 Aug 3;96(16):9305-10.
C61	HAYNES et al., Particle-mediated nucleic acid immunization. J Biotechnol. 1996 Jan 26;44(1-3):37-42.
C62	HEDLEY et al., Microspheres containing plasmid-encoded antigens elicit cytotoxic T-cell responses. Nat Med. 1998 Mar;4(3):365-8.
C63	HOLMGREN et al., Cholera toxin and cholera B subunit as oral-mucosal adjuvant and antigen vector systems. Vaccine. 1993 Sep;11(12):1179-84.
C64	HOPKIN et al., Curbing the CpGs of Bacterial and Viral DNA. BioMedNet. 1999 Jun25; Issue 57.
C65	HORNQUIST et al., Cholera toxin adjuvant greatly promotes antigen priming of T cells. Eur J Immunol. 1993 Sep;23(9):2136-43.
C66	HUANG et al., Induction and regulation of Th1-inducing cytokines by bacterial DNA, lipopolysaccharide, and heat-inactivated bacteria. Infect Immun. 1999 Dec;67(12):6257-63.
C67	HUDSON et al., Nucleic acid dendrimers: Novel biopolymer structures. J Am Chem Soc. 1993;115:2119-24.
<del>-</del>	

EXAMINER:	DATE CONSIDERED:
	<u> </u>

<sup>#</sup> EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)  INFORMATION DISCLOSURE  STATEMENT BY APPLICANT			APPLICATION NO.: 10/023,909		ATTY. DOCKET NO.:	C1039.70058US00	
			FILING DATE:	December 18, 2001	CONFIRMATION NO.	: 8458	
			APPLICANT:	Davis et al.			
			GROUP ART UNIT:	: 1648	EXAMINER:	Jeffrey S. Parkin	
Sheet	8	of	12	GROOF ART UNIT	. 1046	EAAWIINEK.	Jerney S. Farkin

C68	directly on human NK and activated T cells to induce IFN-gamma production in vitro. J Immunol. 1999 Oct 1;163(7):3642-52.	
C69	role for dendritic cells in the augmentation of Th1 responses by immunostimulatory DNA. J Immunol. 1998 Sep 15;161(6):3042-9.	
C76	JAKOB et al., Bacterial DNA and CpG-containing oligodeoxynucleotides activate cutaneous dendritic cells and induce IL-12 production: implications for the augmentation of Th1 responses. Int Arch Allergy Immunol. 1999 Feb-Apr;118(2-4):457-61.	
C7	JONES et al., Poly(DL-lactide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration. Vaccine. 1997  Jun;15(8):814-7.	
C72	JONES et al., Synthetic oligodeoxynucleotides containing CpG motifs enhance immunogenicity of a peptide malaria vaccine in Aotus monkeys. Vaccine. 1999 Aug 6;17(23-24):3065-71.	
C7:	KATAOKA et al., Immunotherapeutic potential in guinea-pig tumor model of deoxyribonucleic acid from Mycobacterium bovis BCG complexed with poly-L-lysine and carboxymethylcellulose.  Jpn J Med Sci Biol. 1990 Oct;43(5):171-82.	<u> </u>
C74	KLINMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.	
C7:	KLINMAN et al., CpG motifs as immune adjuvants. Vaccine. 1999 Jan;17(1):19-25.	
C70	······································	
C7'		
C78	KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen-nonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.	
C79	Application. Crooke, Ed. 1998:243-62.	
C80	KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.	
C8	KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides.  Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.	
C8:	<u> </u>	
C8:	KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.	
C84	KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.	
C8.	KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.	
C80	KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.	
C8	7 KRIEG et al., Infection. In: McGraw Hill Book. 1996:242-3.	

EXAMINER:	DATE CONSIDERED:	

<sup>#</sup> EXAMINER: Initial if reference considered, whether or notitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)				APPLICATION NO	D.: 10/023,909	ATTY. DOCKET N	NO.: C1039.70058US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  Sheet 9 of 12			FILING DATE:	December 18, 2001	CONFIRMATION	NO.: 8458	
			APPLICANT:	Davis et al.	•		
			GROUP ART UNIT	Γ: 1648	EXAMINER:	Jeffrey S. Parkin	
3	,	1 ~ 1					

C88	KRIEG et al., Lymphocyte activation by CpG dinucleotide motifs in prokaryotic DNA. Trends Microbiol. 1996 Feb;4(2):73-6.	
C89	KRIEG, Therapeutic potential of Toll-like receptor 9 activation. Nat Rev Drug Discov. 2006 Jun;5(6):471-84.	
C90	KUKOWSKA-LATALLO et al., Efficient transfer of genetic material into mammalian cells using Starburst polyamidoamine dendrimers. Proc Natl Acad Sci U S A. 1996 May 14;93(10):4897-902.	
C91	KURAMOTO et al., Induction of T-cell-mediated immunity against MethA fibrosarcoma by intratumoral injections of a bacillus Calmette-Guerin nucleic acid fraction. Cancer Immunol Immunother. 1992;34(5):283-8.	
C92	KURAMOTO et al., Changes of host cell infiltration into Meth A fibrosarcoma tumor during the course of regression induced by injections of a BCG nucleic acid fraction. Int J Immunopharmacol. 1992 Jul;14(5):773-82.	
C93	KURAMOTO et al., In situ infiltration of natural killer-like cells induced by intradermal injection of the nucleic acid fraction from BCG. Microbiol Immunol. 1989;33(11):929-40.	· · · · · · · · · · · · · · · · · · ·
C94	LeCLERC et al., The preferential induction of a Th1 immune response by DNA-based immunization is mediated by the immunostimulatory effect of plasmid DNA. Cell Immunol. 1997 Aug 1;179(2):97-106.	
C95	LEE et al., Immuno-stimulatory effects of bacterial-derived plasmids depend on the nature of the antigen in intramuscular DNA inoculations. Immunology. 1998 Jul;94(3):285-9.	
C96	LETSINGER et al., Cholesteryl-conjugated oligonucleotides: synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture. Proc Natl Acad Sci U S A. 1989 Sep;86(17):6553-6.	
C97	LETSINGER et al., Synthesis and properties of modified oligonucleotides. Nucleic Acids Symp Ser. 1991;(24):75-8.	
C98	LIPFORD et al., CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants. Eur J Immunol. 1997 Sep;27(9):2340-4.	
C99	LITZINGER et al., Fate of cationic liposomes and their complex with oligonucleotide in vivo.  Biochim Biophys Acta. 1996 Jun 11;1281(2):139-49.	
C100	LIU et al., Immunostimulatory CpG oligodeoxynucleotides enhance the immune response to vaccine strategies involving granulocyte-macrophage colony-stimulating factor. Blood. 1998 Nov 15;92(10):3730-6.	
C101	LIU et al., CpG ODN is an effective adjuvant in immunization with tumor antigen. J Invest Med. 1997 Sept7;45(7):333A.	
C102	LIU et al., Immunization of non-human primates with DNA vaccines. Vaccine. 1997 Jun;15(8):909-12.	
C103	MacGREGOR et al., First human trial of a DNA-based vaccine for treatment of human immunodeficiency virus type 1 infection: safety and host response. J Infect Dis. 1998 Jul;178(1):92-100.	
C104	MALOY et al., Induction of Th1 and Th2 CD4+ T cell responses by oral or parenteral immunization with ISCOMS. Eur J Immunol. 1995 Oct;25(10):2835-41.	
C105	MARTIN-OROZCO et al., Enhancement of antigen-presenting cell surface molecules involved in cognate interactions by immunostimulatory DNA sequences. Int Immunol. 1999 Jul;11(7):1111-8.	

EXAMINER:	DATE CONSIDERED:

<sup>#</sup> EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)  INFORMATION DISCLOSURE STATEMENT BY APPLICANT			APPLICATION NO.: 10/023,909		ATTY. DOCKET NO.: C1039.70058US00	
			FILING DATE:	December 18, 2001	CONFIRMATION	NO.: 8458
			APPLICANT:	Davis et al.		
			GROUP ART UNIT	Г: 1648	EXAMINER:	Jeffrey S. Parkin
Sheet 10 of 12		droof Art on	1. 1040	EXAMINER.	Jeiney 5. I aikiii	

C1	McCLUSKIE et al., CpG DNA as mucosal adjuvant. Immunol Letts. 1999;69(1):30-1. Abstract #5.2
C1	Immunol. 1999;19(4):303-29.
. C1	antibody complexes. Viral Immunol. 1998;11(4):245-52.
· C1	mice and non-human primates. Mol Med. 1999 May;5(5):287-300.
. C1	Jul;1(9):685-98.
C1	Vaccine. 1992;10(2):75-88.
C1	OKADA et al., Bone marrow-derived dendritic cells pulsed with a tumor-specific peptide elicit effective anti-tumor immunity against intracranial neoplasms. Int J Cancer. 1998 Oct 5;78(2):196-201.
CI	antiviral immune responses with T-cell peptide vaccines. J Virol. 1999 May;73(5):4120-6.
C1	27;772:152-63.
C1	Immunol Res. 1999;19(1):35-46.
C1	PISETSKY et al., Immune activation by bacterial DNA: a new genetic code. Immunity. 1996 Oct;5(4):303-10.
C1	PISETSKY et al., The influence of base sequence on the immunological properties of defined oligonucleotides. Immunopharmacology. 1998 Nov;40(3):199-208.
C1	ROBERTSON et al., Crohn's trial shows the pros of antisense. Nat Biotechnol. 1997 Mar;15(3):209.
C1	19 ROBINSON, Nucleic acid vaccines: an overview. Vaccine. 1997 Jun;15(8):785-7.
C1	SANDS et al., Biodistribution and metabolism of internally 3H-labeled oligonucleotides. I.  Comparison of a phosphodiester and a phosphorothioate. Mol Pharmacol. 1994 May;45(5):932-43.
C1	SCHWARTZ et al., Bacterial DNA or oligonucleotides containing unmethylated CpG motifs can minimize lipopolysaccharide-induced inflammation in the lower respiratory tract through an IL-12-dependent pathway. J Immunol. 1999 Jul 1;163(1):224-31.
C1	SIDMAN et al., Gamma-interferon is one of several direct B cell-maturing lymphokines. Nature. 1984 Jun 28-Jul 4;309(5971):801-4.
Cı	SONEHARA et al., Hexamer palindromic oligonucleotides with 5'-CG-3' motif(s) induce production of interferon. J Interferon Cytokine Res. 1996 Oct;16(10):799-803.
CI	24 SPARWASSER et al., Bacterial DNA causes septic shock. Nature. 1997 Mar 27;386(6623):336-7.
C1	
C1	

EXAMINER:	DATE CONSIDERED:

<sup>#</sup> EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)				APPLICATION NO	D.: 10/023,909	ATTY. DOCKET NO.:	C1039.70058US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  Sheet 11 of 12			FILING DATE:	December 18, 2001	CONFIRMATION NO	: 8458	
			APPLICANT:	Davis et al.			
			CDOLID ADTIBUT	r. 1640	EVALUED.	Jackens C. Daulain	
			GROUP ART UNI	T: 1648	EXAMINER:	Jeffrey S. Parkin	

C	STAATS et al., Mucosal immunity to infection with implications for vaccine development. Curr Opin Immunol. 1994 Aug;6(4):572-83.
C	STEIN et al., Problems in interpretation of data derived from in vitro and in vivo use of antisense oligodeoxynucleotides. Antisense Res Dev. 1994 Summer;4(2):67-9.
. C	STEIN et al., Non-antisense effects of oligodeoxynucleotides. Antisense Technology. 1997; ch11: 241-64.
C	SUN et al. Type I interferon-mediated stimulation of T cells by CpG DNA. J Exp Med. 1998 Dec 21;188(12):2335-42.
C	SUN et al., DNA as an adjuvant: capacity of insect DNA and synthetic oligodeoxynucleotides to augment T cell responses to specific antigen. Exp Med. 1998 Apr 6;187(7):1145-50.
Cl	TACKET et al., Phase 1 safety and immune response studies of a DNA vaccine encoding hepatitis B surface antigen delivered by a gene delivery device. Vaccine. 1999 Jul 16;17(22):2826-9.
C	TOKUNAGA et al., Synthetic oligonucleotides with particular base sequences from the cDNA encoding proteins of Mycobacterium bovis BCG induce interferons and activate natural killer cells.  Microbiol Immunol. 1992;36(1):55-66.
C	UGEN et al., DNA vaccination with HIV-1 expressing constructs elicits immune responses in humans. Vaccine. 1998 Nov;16(19):1818-21.
C	VLASSOV et al., In Vivo pharmocokinetics of oligonucleotides following administration by different routes. CRC Press, Inc. Chapter 5. 1995:71-83.
C	WANG et al., Induction of antigen-specific cytotoxic T lymphocytes in humans by a malaria DNA vaccine. Science. 1998 Oct 16;282(5388):476-80.
C	WEERATNA et al., Reduction of antigen expression from DNA vaccines by coadministered oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Aug;8(4):351-6.
C	WEINER et al., Immunostimulatory oligodeoxynucleotides containing the CpG motif are effective as immune adjuvants in tumor antigen immunization. Proc Natl Acad Sci U S A. 1997 Sep 30;94(20):10833-7.
C	WHALEN et al., DNA-mediated immunization to the hepatitis B surface antigen. Activation and entrainment of the immune response. Ann N Y Acad Sci. 1995 Nov 27;772:64-76.
C	WHITESELL et al., Stability, clearance, and disposition of intraventricularly administered oligodeoxynucleotides: implications for therapeutic application within the central nervous system. Proc Natl Acad Sci U S A. 1993 May 15;90(10):4665-9.
C	YEW et al., Contribution of plasmid DNA to inflammation in the lung after administration of cationic lipid:pDNA complexes. Hum Gene Ther. 1999 Jan 20;10:223-34.
C	YI et al. Rapid induction of mitogen-activated protein kinases by immune stimulatory CpG DNA. J Immunol. 1998 Nov 1;161(9):4493-7.
C	YI et al., CpG DNA rescue of murine B lymphoma cells from anti-IgM-induced growth arrest and programmed cell death is associated with increased expression of c-myc and bcl-xL. J Immunol. 1996 Dec 1;157(11):4918-25.
C	YI et al. CpG oligodeoxyribonucleotides rescue mature spleen B cells from spontaneous apoptosis and promote cell cycle entry. J Immunol. 1998 Jun 15;160(12):5898-906.
C	ZHAO et al., Pattern and kinetics of cytokine production following administration of phosphorothioate oligonucleotides in mice. Antisense Nucleic Acid Drug Dev. 1997 Oct;7(5):495-502.

EXAMINER:	DATE CONSIDERED:

<sup>#</sup> EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

EODM DTO 1440/4 and D (madified DTO/CD/09)	APPLICATION NO.: 10/023,909	ATTY. DOCKET NO.: C	C1039.70058US00
FORM PTO-1449/A and B (modified PTO/SB/08)  INFORMATION DISCLOSURE	FILING DATE: December 18, 2001	CONFIRMATION NO.: 8458	
STATEMENT BY APPLICANT	APPLICANT: Davis et al.		
Sheet 12 of 12	GROUP ART UNIT: 1648	EXAMINER:	Jeffrey S. Parkin
	of oligonucleotide-induced immune stimu 6 Nov 22;52(10):1537-44.	ation by cyclodextrin analogue.	ogs.
filing date under 35 U.S.C. 120 (continuation, continuation-in-in-in-in-in-in-in-in-in-in-in-in-in	ications, or pending, unpublished patent applications other patent(s), publication(s), unpublished, pending	U.S. patent applications, or other	information listed are
EXAMINER:	DATE CONSIDERED	:	

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.